DEPARTMENT OF HEALTH & HUMAN SERVICES

HFI-35
m2288

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

WARNING LETTER

January 5, 1999

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Edward J. Arkans, President
ACI Medical, Inc.
1857 Diamond Street
San Marcos, CA 92069

WL 16-9

Dear Mr. Arkans:

We are writing to you because during an inspection of your firm conducted between November 9 to 25, 1998, our investigator determined that your firm manufactures and distributes pneumatic compression devices.

Under the United States Federal law, these products are considered to be medical devices as that term is defined by section 201 (h) of the Federal Food, Drug and Cosmetic Act (the Act).

Our inspection revealed that these devices are adulterated within the meaning of Section 501 (h) of the Act, in that the methods used in, and the facilities and controls used for the design, manufacture, packaging, labeling, storage, installation, or servicing are not in conformance with the Good Manufacture Practice (GMP) requirements set forth in the Quality System Regulation as specified in Title 21 Code of Federal Regulations, (CFR) Part 820, as follows:

1. Failure to control procedures for receiving, reviewing, and evaluation of complaints and maintain records of investigations of all complaints involving the possible failure of a device and/or records describing the reason no investigation was made [21 CFR 820.198 (b)]. For example, our investigation disclosed that your firm had no written documentation describing the rationale for not performing investigations or documenting the results of investigations of several reported complaints, specifically devices returned for repairs, regardless of their warranty status.

2. Failure to control procedures to ensure that all documents required by the Quality System Regulation have been properly reviewed for adequacy and approved prior to issuance [21 CFR 820.40]. For example, our investigation

disclosed changes were made to quality system documents without going through any approval process.

3. Failure to maintain device master records which contains a compilation of records containing the procedures and specifications for a finished device [21 CFR 820.181]. For example, our investigation determined that your device master records for your air-plethysomograph device does not contain all approved engineering and drawing changes. Also, the device master record for the ArtAssist arterial assist device does not contain manufacturing and testing instructions.

We acknowledge that you have submitted to this office a response concerning our investigator's observations noted on the form FDA 483. Whereas, your response indicates that corrective measures were undertaken by your company, no supporting materials were included with your November 30, 1998 response, therefore, the adequacy of your response could not be evaluated. We will appreciate you providing these materials to us, with your response to this letter.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the form FDA-483 issued at the conclusion of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems problems, you must promptly initiate permanent corrective actions.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, injunction, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts or approving requests for Certificates to Foreign Governments for Export.

It is necessary for you to take action on this matter. Please notify this letter, of the specific steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time, state the reason for the delay and the time within the corrections will be completed.

Please submit your response to:

Dannie E. Rowland, Compliance Officer
U. S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, CA 92612-2445

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting DSMA at phone number: 1-800-638-2041, FAX: 301-443-8818, or through our Internet website at http://www.fda.gov/cdrh

Sincerely,

Elaine C. Messa
District Director

cc: State Department of Public Health
Environmental Health Services
Attn: Chief Food and Drug Branch
601 North 7th Street, MS-357
P.O. Box 942732
Sacramento, CA 94234